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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,223

Applicant(s)

TINIUS, CHRISTOPHER

Examiner

Ashwin Mehta

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4152005 & 12062005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Request under 37 CFR 1.105.

DETAILED ACTION

Claim Objections

1. Claims 1, 2, 7, 12, and 14 are objected to for containing a blank line. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/412,724 (‘724). Although the conflicting claims are not identical, they are not patentably distinct from each other because soybean variety “6190006” of instant claim 1 appears to the

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same as soybean variety “7085005” of claim 1 of ‘724. The Variety Description Information for 6190006 on pages 10-11 of the instant specification, and for 7085005 on pages 10-11 of the specification in ‘724, do not render the two varieties patentably distinct. 7085005 is resistant to Races 1 and 2, and susceptible to Race 3, of phytophthora root rot. Information regarding phytophthora root rot is missing from the instant Variety Description Information. ‘724 indicates 7085005 has black hilum color, whereas the hilum color for 6190006 is described as ranging from brown to black with varying levels of black intensity. However, this does not appear to be a significant difference. It is not clear that the hilum color 6190006 could not have been described as black, given that the soybean line is supposed to be uniform and stable (page 9, paragraph [0055]). The other traits listed in the Variety Description Information for 6190006 are also possessed by 7085005, or are traits that vary depending on environmental influences. Instant claims 2-20 which depend from claim 1, have the same limitations as claims 2-15 and 18-22 of ‘724.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 1, 2, 7, 12, and 14: the claims are indefinite for the recitation, “6190006”. This is an arbitrarily assigned name for a soybean variety. It does not define any traits possessed by the variety. This name can also be changed or arbitrarily assigned to any other plant line. Inclusion of the ATCC accession number into the claims will obviate the rejection.

In claim 6: the recitation, “said cell or protoplast of the tissue culture is” renders the claim indefinite. There is improper antecedent basis for the recitation, because parent claim 5 recites “cells” (plural) whereas the recitation in claim 6 recites “cell or a protoplast” (singular). The following amendment is suggested as a replacement: --cells, or protoplasts thereof, are--.

In claim 7: the recitation “is capable of expressing” in line 2 renders the claim indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation, be replaced with --has--.

In claim 11: the claim is indefinite because it appears to be missing a step. The claim indicates that the method is for producing a soybean seed by growing the hybrid plant of claim 10. However, seed will not be produced if the plant is not pollinated. The claim does not recite any such step.

In claim 12: the recitation, “The method for producing a soybean variety 6190006-derived soybean plant” renders the claim indefinite. It is unclear if the soybean variety 6190006-derived soybean plant is an F1 generation plant. If it is, it is suggested that --F1 generation-- be inserted in line 1 after “variety”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-15 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification describes some characteristics of a soybean plant designated “6190006” (pages 9-10 and 28-30).

A review of the full content of the specification indicates that seed of soybean plant 6190006, hybrid seed produced by crossing a 6190006 plant with any other soybean plant, and the seed and plants of subsequent generations, are essential to the operation and function of the claimed invention.

A review of the language of claims 9-10 indicates that the claims are drawn to a genus, i.e., any and all hybrid soybean seeds, and the hybrid soybean plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing soybean plant 6190006 with a second, distinct soybean plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-6190006 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-6190006 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ. A review of the language of claim 11 indicates that it requires the hybrid soybean

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plant of claim 10 as starting material in a method for producing seed by growing said hybrid plant. Note that the seed produced by the method of claim 11 would be a second generation, since a crossing step would be required for the seed to be produced.

A review of the language of claim 12 indicates that it is drawn to a method for producing 6190006-derived soybean plants, and claim 13 is drawn towards the plant produced by that method. Claim 12 recites only one crossing step, which indicates that the 6190006-derived plant is an F1 generation. However, it is unclear if the method is limited to producing only F1 generation plants (see the indefinite rejection above), and whether other crossing steps are encompassed.

A review of the language of claim 14 indicates that it is also drawn to a method for producing 6190006-derived soybean plants, wherein the method comprises selfing F1 generation plants for several generations. The claim therefore requires F1 generation plants and plants of subsequent generations. Claim 15 is directed to a genus, i.e. any plant produced by that method.

The specification does not describe any hybrid soybean plants produced by crossing 6190006 with any soybean plant. The specification does not describe a single 6190006-derived soybean plant, of F1 or any subsequent generation. Hybrids produced by crossing 6190006 with other soybean plants would, of course, produce plants that do not express the same traits as 6190006. The description of 6190006 and the limited information regarding its traits on pages 9-11 and 28-29 of the specification do not provide any information concerning the morphological and physiological characteristics of its descendants. In view of these considerations, a person of skill in the art would not have viewed the disclosure as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced from 6190006.

As the plants of the F1 and subsequent generations are required for the claimed methods, the methods are not described, either. The Federal Register (64 Fed. Reg. 71427, 71428 (1999), Comment No. 4) indicates that a suggestion was made that the written description guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those whose patentability rests in the steps of the process itself, and that this suggestion was adopted. The patentability of the method claims do not lie in the method steps, which require the simple acts of crossing plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method claims are not described, as the specification does not sufficiently describe the genus of hybrid plants, and any progeny of subsequent generations, for the reasons discussed above.

Claim 18 is drawn towards a method of producing a soybean plant comprising crossing 6190006 with any soybean containing any transgene. A review of the claim indicates that there is no limit as to the identity of the transgene, and it can therefore express any trait, or no trait at all. However, the specification does not describe isolated transgenes for all soybean plant traits. The specification does not describe single transgenes that have the ability to alter all given soybean plant traits. Claim 20 is directed to soybean plants produced by the method of claim 18. The plants of claim 20 are not described, as the effect on the plant exerted by the transgene is not described. The plants are also not described, as they are F1 generation plants. Given the breadth of the claims, it is submitted that the specification fails to provide an adequate written description of the multitude of soybean plants and their parts encompassed by the claims.

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5. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards seed of soybean line 6190006; or a soybean plant produced by growing said seed; tissue culture of regenerable cells from said soybean plant; a method for producing hybrid soybean seed; a method for producing a soybean plant that contains in its genetic material a transgene; a hybrid soybean seed produced by crossing soybean variety 6190006 with a second soybean plant; a hybrid soybean plant produced by growing said hybrid seed; a method of producing a soybean seed by growing said hybrid plant; a method for producing a 6190006-derived soybean plant, comprising crossing soybean line 6190006 with a second soybean plant, growing the progeny seed to yield a 6190006-derived soybean plant, selfing said plant to yield additional 6190006-derived progeny soybean seed, and growing said seed and repeating the crossing and growing steps for 0 to 7 times; a 6190006-derived soybean plant produced by said method; or a method comprising crossing 6190006 with any soybean plant containing any transgene, and plants produced by said cross.

The claimed seed of soybean variety 6190006 is essential to the claimed invention. It must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily

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available to the public. A deposit of the seeds of inbred soybean line 6190006 with an acceptable depository is required.

If the seeds will be deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained. See 37 CFR 1.801-1.809.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9-11, 13, and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shannon et al. (U.S. Patent No. 6,011,204, issued January 4, 2000).

The claims are broadly drawn towards any hybrid soybean seed, plant, or parts thereof, produced by crossing a first soybean plant with soybean designated "6190006", or further wherein the progeny seed of the cross is grown and selfed, and crossed again with another soybean plant, and selfed again, 0 to 7 times; or soybean plants produced by crossing plant 6190006 with any transgenic soybean plant, wherein the progeny contain the transgene.

Shannon et al. teach hybrid soybean seeds, and soybean plants produced by growing said seed, parts of said plant, and seed produced by said hybrid plant (claims). The soybean seeds, plants, and plant parts may have been produced from a method different from those of the instantly claimed soybean seeds, plants and plant parts. However, the instantly claimed products do not appear to differ from the products taught by the reference. "[E]ven though product-by-

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process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The instant claims do not recite any limitation(s) that would distinguish the products from those of the reference. The reference also teaches seeds produced by the claimed hybrid plants, and methods of breeding, which comprise crossing a hybrid soybean plant with another plant, to obtain the next generation (col. 2, line 47 to col. 3, line 44). Such method steps inherently encompass growing hybrid seed to produce a hybrid plant, crossing with another soybean plant, and harvesting the resultant seed.

7. Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McCabe et al. (Bio/Technology, 1988, Vol. 6, pages 923-926).

The claim is drawn towards any soybean plant, or parts thereof, produced by the method of claim 18.

McCabe et al. teach a transgenic soybean plant, comprising a transgene (pages 923-925). The soybean plant taught in the reference was not produced by the same method as the claimed soybean plant. However, the instantly claimed products do not appear to differ from the products taught by the reference. See *In re Thorpe, supra*.

8. Claims 1-20 are rejected.

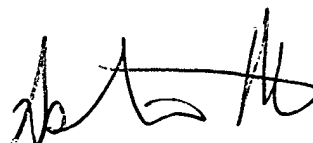
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Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

March 15, 2006



Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

ATTACHMENT TO OFFICE ACTION

Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming a seed comprising at least one set of the chromosomes of soybean line 6190006. Applicant is claiming a soybean comprising at least 95% of the alleles of soybean plant line 6190006, **but** the instant specification is silent about what starting materials and methods were used to produce soybean line 6190006. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental soybean lines used to produce soybean line 6190006? Please supply all of the designations/denominations used for the original parental soybean lines and line 6190006. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce soybean line 6190006?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental soybean lines or progeny therefrom been disclosed or made publicly available? If so, under what

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designation/denomination and under what conditions were said parental soybean lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other soybean lines produced by said method using said original parental soybean lines, and if so, had said produced soybean lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other soybean lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

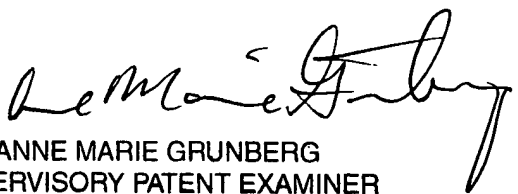
4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

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6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.



ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER